

Amendment and Response

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Confirmation No.: 2943

Filed: May 25, 2007

For: ACCOUNTO-MECHANICAL DETECTION SYSTEMS AND METHODS OF USE

Amendments to the Drawings

The attached sheets of drawings include corrections to Figures 1, 2, 4D, 4F, 7, 8, 8C, and 10C. These sheets, which include Figures 1-12, replace the original sheets including Figures 1-12. The corrections made to Figures 1, 2, 4D, 4F, 7, 8, 8C, and 10C are described below:

- Figure 1: Reference number 10 has been added.
- Figure 2: Reference number 110 has been added.
- Figure 4D: Reference numbers 260d and 262d have been added.
- Figure 4F: Reference number 260f has been added.
- Figure 7: Reference number 563 has been added.
- Figure 8: Reference number 612 has been added.
- Figure 8C: Reference numbers 651a and 651b have been deleted.
- Figure 10C: Reference number 1695 has been added.

Attachment: Replacement Sheets

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Remarks

The Office Action mailed October 22, 2009 has been received and reviewed. Claims 1, 7, 11, and 12 have been amended, claims 23-47 have been canceled (without prejudice), and new claims 48-65 are presented. Upon entry of these amendments, claims 1-22 and 48-65 will be pending, with claims 4-5 and 59-60 withdrawn from consideration. Reconsideration and withdrawal of the rejections are respectfully requested.

Claims 59-60

Applicants have presented new claims 59-60 which parallel withdrawn claims 4-5 for the purpose of retaining a complete set of claims pending from new independent claim 53.

Applicants understand that claims 59-60 should be considered as withdrawn from consideration in view of Applicants' earlier election of species that resulted in the withdrawal of claims 4-5. Nonetheless, Applicants have submitted claims 59-60 as "New" in this response because they have not been previously presented. Correction of the status of claims 59-60 is respectfully requested if necessary to enter the claims.

Correction of Inventorship

On February 22, 2008 Applicants filed a Request to Correct Inventorship Under 37 CFR §1.48(a). Applicants respectfully request consideration and approval of the Request.

Claim Objections

Applicants respectfully submit that the objections to claims 1, 11, and 12 are addressed by the amendments to each of those claims. Reconsideration and withdrawal of the claim objections are, therefore, respectfully requested.

Drawing Objections

Applicants are presenting revised Figures 1, 2, 4D, 4F, 7, 8, 8C, and 10C to address the objections raised with respect to those figures in the Office Action. Applicants respectfully

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submit that these revisions are supported in the application as filed at the locations noted by the Examiner in the Office Action. Entry and approval of the revised figures are respectfully requested.

With respect to the objection regarding Figures 10A and 10B, Applicants have presented an amendment to page 45 of the specification inserting the missing reference number "895" as seen in Figures 10A and 10B. Entry and approval of this amendment is respectfully requested.

Objection to the Specification

Applicants have presented amendments to the specification to address the issues raised on page 4 of the Office Action. Entry of these amendments are respectfully requested.

Claim Amendments

Applicants respectfully submit that the amendments to claim 1 are supported by the application as filed at, e.g., claim 1 as originally filed, as well as in the specification at, e.g., page 4, lines 27-33; page 19, line 12 to page 23, line 19; page 26, line 8 to page 32, line 29.

Applicants respectfully submit that the amendments to claims 7, 11 and 12 are supported by, e.g., the claims as originally filed.

Applicants respectfully submit that new claims 48-50 are supported in the application as filed at, e.g., the original claims 8 and 9 and in the specification at page 40, lines 10-23. Furthermore, Applicants respectfully submit that new claims 48-50 fall within the scope of the elected group and species.

Applicants respectfully submit that new claims 51-52 are supported in the application as filed at, e.g., the original claims 12 and 18 and in the specification at page 44, lines 25-28. Furthermore, Applicants respectfully submit that new claims 51-52 fall within the scope of the elected group and species.

Applicants respectfully submit that new claims 53-65 are supported in the application as filed at, e.g., the original claims 1-22 and in the specification at page 40, lines 10-23; page 44, lines 25-28; etc. Furthermore, Applicants respectfully submit that new claims 53-58 and 61-65

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fall within the scope of the elected group and species and that, as indicated above, claims 59-60 should be withdrawn as falling outside the scope of the elected species.

The 35 U.S.C. §112, Second Paragraph, Rejection

Claims 1 and 7 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants respectfully submit that the amendment made to claim 1 deleting the phrase "shear horizontal" addresses the basis for this rejection as applied to claim 1. Further, Applicants respectfully submit that the amendment to claim 7 replacing the term "cartridge" with "system" addresses this rejection as applied to claim 7.

In view of the amendments to claims 1 and 7, Applicants submit that the claims to comply with the requirements of § 112. Reconsideration and withdrawal of the § 112 rejection of claims 1 and 7 are, therefore, respectfully requested.

The 35 U.S.C. §102 Rejection

Claims 1-3, 7, and 12-15 were rejected under 35 U.S.C. §102(e) as being anticipated by Hunt et al. (US 2008/0138797). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Claim 1, from which all of claims 2, 3, and 12-15 depend, recites a system for detecting a target biological analyte that includes, *inter alia*, a detection chamber that includes a volume defined by the detection surface of a surface acoustic wave sensor and an opposing surface that includes a flow front control feature. The system further includes a waste chamber in fluid communication with the detection chamber.

In support of the anticipation rejection of claims 1-3, 7, and 12-15 over Hunt et al. it is asserted that Hunt et al. teaches a flow front control feature in the form of "transducers and/or binding agents." *Office Action*, page 6 (October 22, 2009). Applicants respectfully disagree.

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Although the "flow front control feature" recited in claim 1 is described in the application as filed, Applicants have amended claim 1 to explicitly recite the function of that feature, namely that the flow front control feature "controls progression of a leading edge of a bolus of material moving across the detection surface."

In contrast, Hunt et al. does not teach that the "transducers and/or binding agents" perform as a "flow front control feature" as asserted in support of this anticipation rejection. In fact, Hunt et al. is silent as to the need to control the progression of fluid over the detector surfaces.

Although not explicitly stated, if it is the intent of the Examiner to assert that the "transducers and/or binding agents" inherently functions as a "flow front control feature" Applicants respectfully submit that the requirements for a rejection based on inherency have not been met. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112(IV), p. 2100-47, 8th Ed., Rev. 6, (Sept. 2007) (emphasis in original) (*citing In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993)). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Id.* at p. 2100-48 (*citing Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)).

In the present rejection, no evidence or technical reasoning has been provided to show that the "transducers and/or binding agents" necessarily serve as "a flow front control feature that controls progression of a leading edge of a bolus of material moving across the detection surface." For at least this reason, Applicants respectfully submit that the anticipation rejection of claims 1-3, 7, and 12-15 is improper and should be withdrawn.

With respect to claim 7, Applicants respectfully submit that the "port 206" of Hunt et al. is not described as a "capillary structure" as asserted in the Office Action. If it is the intent of the Examiner to assert that the port 206 inherently forms a "capillary structure," then the requirements for a rejection based on inherency (as discussed above) have not been met. In

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particular, no evidence or technical reasoning has been provided to show that the port 206 is necessarily a "capillary structure" as recited in claim 7. In addition to the reasons presented above, Applicants respectfully submit that the anticipation rejection of claim 7 is improper and should be withdrawn.

For at least the reasons presented above, Applicants respectfully submit that claims 1-3, 7, and 12-15 are patentable over Hunt et al. under 35 U.S.C. § 102. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

The 35 U.S.C. §103 Rejections**Claims 1-3, 6-8 and 12-17**

Claims 1-3, 6-8, and 12-17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Claim 1, from which all of claims 2, 3, 6-8, and 12-17 depend, recites a system for detecting a target biological analyte that includes, *inter alia*, a detection chamber that includes a volume defined by the detection surface of a surface acoustic wave sensor and an opposing surface that includes a flow front control feature. The system further includes a waste chamber in fluid communication with the detection chamber.

In support of the obviousness rejection of claims 1-3, 6-8, and 12-17 over Warthoe et al. in view of Buechler, it is asserted that Buechler teaches a flow front control feature in the form of "fluid control means 18" and that one of ordinary skill in the art would be motivated to include the fluid control means of Buechler in the apparatus of Warthoe et al. *Office Action*, pages 9-10 (October 22, 2009). Applicants respectfully submit, however, that a *prima facie* case of obviousness has not been established for claims 1-3, 6-8, and 12-17 over Warthoe et al. in view of Buechler.

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To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1970). Further, the Board of Patent Appeals and Interferences has confirmed that all claim limitations must be taught or suggest by the prior art to establish a case of *prima facie* obviousness as shown in the following excerpt:

When determining whether a claim is obvious, an examiner must make 'a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.' *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, 'obviousness requires a suggestion of all limitations in a claim.' *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (*citing In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).
In re Wada, Appeal 2007-3733, Application 10/613,220, (B.P.A.I. 2008).

Applicants respectfully submit that, in connection with this obviousness rejection, all of the claim limitations are not taught or suggested by the prior art. In particular, Applicants respectfully submit that the "flow front control feature" recited in claim 1 is not taught or suggested by the cited references. Applicants have amended claim 1 to explicitly recite the function of the flow front control feature, namely that the flow front control feature "controls progression of a leading edge of a bolus of material moving across the detection surface."

The "fluid control means 18" of Buechler et al. is not, however, described as controlling progression of a leading edge of a bolus of material moving across the diagnostic element 6. Rather, as described in Buechler, the fluid control means 18 "causes the volume of the reaction mixture to flow over the capture zone of the diagnostic element 6 at a rate which allows for an optimum capture of reagents onto the capture zone." *Buechler*, column 14, lines 57-60. More specifically, the fluid control means 18 is described as functioning to slow the rate of fluid flow over the diagnostic element 6 after the fluid has already passed over the surface of the diagnostic element 6. *See, e.g., Buechler*, column 15, lines 4-12 and lines 24-29; column 22, lines 29-45. In other words, the fluid control means 18 cannot control the progression of the leading edge of the fluid over the diagnostic element 6 because the fluid has already passed over the surface of the diagnostic element 6.

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Although not explicitly stated, if it is the intent of the Examiner to assert that the "fluid control means 18" of Buechler inherently functions as a "flow front control feature," Applicants respectfully submit that the requirements for a rejection based on inherency have not been met. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112(IV), p. 2100-47, 8th Ed., Rev. 6, (Sept. 2007) (emphasis in original) (*citing In re Rijckaert*, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993)). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Id.* at p. 2100-48 (*citing Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)).

In the present rejection, no evidence or technical reasoning has been provided to show that the "fluid control means 18" necessarily serves as "a flow front control feature that controls progression of a leading edge of a bolus of material moving across the detection surface" as recited in claim 1.

For at least these reasons, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to claims 1-3, 6-8, and 12-17.

In addition to the reasons presented above with respect to all of claims 1-3, 6-8, and 12-17, claim 3 recites that "the flow front control feature comprises discrete structures protruding from and separated by a land area on the opposing surface of the detection chamber." The only "fluid control means 18" disclosed or suggested by Buechler is a gap or slot formed between elements 8 and 9 in, e.g., Figure 1D of Buechler. Contrary to the assertion made in the Office Action, Buechler does not teach "that the flow control means can comprise discrete structures protruding from and separated by a land area on the opposing surface of the diagnostic element." *Office Action*, page 10 (October 22, 2009). Applicants respectfully submit that this shortcoming provides additional support for Applicants' position that a *prima facie* case of obviousness has not been established with respect to claim 3.

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In addition to the reasons presented above with respect to all of claims 1-3, 6-8, and 12-17, claim 16 recites a sealed module attached to the housing containing the detection chamber, where the sealed module itself contains "a first chamber comprising a liquid located therein; a second chamber comprising a selected reagent located therein; and an inter-chamber seal isolating the second chamber from the first chamber within the at least one module." Applicants note that none of the cited portions of Warthoe et al. teach or suggest this combination of features in one sealed module (nor does Buechler address these features either). Applicants respectfully submit that this shortcoming provides additional support for Applicants' position that a *prima facie* case of obviousness has not been established with respect to claim 16.

For at least the reasons presented above, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to claims 1-3, 6-8, and 12-17 over Warthoe et al. in view of Buechler. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

Claim 9

Claim 9 was rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270), as applied to claims 1 and 8 above, and further in view of Hodges et al. (US 2003/0180814). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Claim 9 depends from claim 8 which, in turn, depends from claim 1. As discussed above, the combination of Warthoe et al. in view of Buechler does not support a *prima facie* case of obviousness with respect to claims 1 and 8. In connection with the rejection of claim 9, Applicants further note that Hodges et al. does not address the deficiencies in the *prima facie* case of obviousness of claims 1 and 8. For at least that reason, Applicants respectfully submit that the combination of Hodges et al. with Warthoe et al. and Buechler also does not establish a *prima facie* case of obviousness with respect to claim 9. Reconsideration and withdrawal of the obviousness rejection of claim 9 are, therefore, respectfully requested.

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For: ACCOUNTO-MECHANICAL DETECTION SYSTEMS AND METHODS OF USE**Claim 10**

Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270), as applied to claim 1 above, and further in view of Beebe et al. (US 2003/0077836). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Claim 10 depends from claim 1. As discussed above, the combination of Warthoe et al. in view of Buechler does not support a *prima facie* case of obviousness with respect to claim 1. In connection with the rejection of claim 10, Applicants further note that Beebe et al. does not address the deficiencies in the *prima facie* case of obviousness of claim 1. For at least that reason, Applicants respectfully submit that the combination of Beebe et al. with Warthoe et al. and Buechler also does not establish a *prima facie* case of obviousness with respect to claim 10. Reconsideration and withdrawal of the obviousness rejection of claim 10 are, therefore, respectfully requested.

Claim 11

Claim 11 was rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270), as applied to claim 1 above, and further in view of Ohman et al. (US 2005/0042766). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Claim 11 depends from claim 1. As discussed above, the combination of Warthoe et al. in view of Buechler does not support a *prima facie* case of obviousness with respect to claim 1. In connection with the rejection of claim 11, Applicants further note that Ohman et al. does not address the deficiencies in the *prima facie* case of obviousness of claim 1. For at least that reason, Applicants respectfully submit that the combination of Ohman et al. with Warthoe et al. and Buechler also does not establish a *prima facie* case of obviousness with respect to claim 11. Reconsideration and withdrawal of the obviousness rejection of claim 11 are, therefore, respectfully requested.

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Claims 18 and 19

Claims 18 and 19 were rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270), as applied to claim 1 above, and further in view of Tisone (US 2006/0292304). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Claim 18 depends from claim 12 which, in turn, depends from claim 1 and claim 19 depends directly from claim 18. As discussed above, the combination of Warthoe et al. in view of Buechler does not support a *prima facie* case of obviousness with respect to claims 1 and 12. In connection with the rejection of claims 18 and 19, Applicants further note that Tisone does not address the deficiencies in the *prima facie* case of obviousness of claims 1 and 12. For at least that reason, Applicants respectfully submit that the combination of Tisone with Warthoe et al. and Buechler also does not establish a *prima facie* case of obviousness with respect to claims 18 and 19.

In addition, Applicants submit that, despite assertions to the contrary, Tisone does not teach or suggest "an exit seal closing the exit port" of a module, nor does Tisone teach or suggest that "movement of the plunger towards the exit port opens the exit seal." Although a variety of paragraphs and figures from Tisone are cited in support of this obviousness rejection, a careful review of the cited portions reveals no exit seal or opening of the exit seal by advancement of a plunger.

The failure of the cited references to teach or suggest all of the features recited in claims 18 and 19 provides additional support for Applicants' position that a *prima facie* case of obviousness has not been established with respect to claims 18 and 19 over Warthoe et al. in view of Buechler and Tisone. Reconsideration and withdrawal of the obviousness rejection of claims 18 and 19 are, therefore, respectfully requested.

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Claim 22

Claim 22 was rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270), as applied to claim 1 above, and further in view of Tisone (US 2006/0292304). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Claim 22 depends from claim 1. As discussed above, the combination of Warthoe et al. in view of Buechler does not support a *prima facie* case of obviousness with respect to claim 1. In connection with the rejection of claim 22, Applicants further note that Tisone does not address the deficiencies in the *prima facie* case of obviousness of claim 1. For at least that reason, Applicants respectfully submit that the combination of Tisone with Warthoe et al. and Buechler also does not establish a *prima facie* case of obviousness with respect to claim 22.

In addition, Applicants submit that, despite assertions to the contrary, Tisone does not teach or suggest at least the following features recited in claim 22: a) "an exit seal located over the exit port" of a module, b) "an input port in fluid communication with the chamber, wherein the input port enters chamber between the plunger and the exit port when the plunger is in the loaded position" in the module, or c) "movement of the plunger towards the exit port opens the exit seal." Although a variety of paragraphs and figures from Tisone are cited in support of this obviousness rejection, a careful review of the cited portions reveals no teachings or suggestions regarding at least these features in Tisone.

The failure of the cited references to teach or suggest all of the features recited in claim 22 provides additional support for Applicants' position that a *prima facie* case of obviousness has not been established with respect to claim 22 over Warthoe et al. in view of Buechler and Tisone. Reconsideration and withdrawal of the obviousness rejection of claim 22 are, therefore, respectfully requested.

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Claims 20 and 21

Claims 20 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Warthoe et al. (US 2004/0072208) in view of Buechler (U.S. Patent No. 6,156,270) and Tisone US 2006/0292304), as applied to claims 18 and 19 above, and further in view of Beebe et al. (US 2003/0077836). Applicants respectfully disagree with this rejection and the assertions made in support of it.

Claim 20 depends from claim 19 which, in turn, depends from claim 18, which in turn depends from claim 12 which, in turn depends from claim 1 and claim 21 depends directly from claim 20. As discussed above, the combination of Warthoe et al. in view of Buechler does not support a *prima facie* case of obviousness with respect to claims 1 and 12, nor does the combination of Warthoe et al. in view of Buechler and Tisone support a *prima facie* case of obviousness with respect to claims 18 and 19. In connection with the rejection of claims 20 and 21, Applicants further note that Tisone does not address the deficiencies in the *prima facie* case of obviousness of claims 1, 12, 18 or 19. For at least that reason, Applicants respectfully submit that the combination of Tisone with Warthoe et al. and Buechler also does not establish a *prima facie* case of obviousness with respect to claims 20 and 21.

Reconsideration and withdrawal of the obviousness rejection of claims 20 and 21 are, therefore, respectfully requested.

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Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 22nd day of March, 2010.

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ATTACHMENT - REPLACEMENT SHEETS

Serial No.: 10/596,956

Docket No.: 59468US005

Pursuant to 37 C.F.R. §1.121(d), attached are amended Figures 1, 2, 4D, 4F, 7, 8, 8C, and 10C, labeled "Replacement Sheets," which replace the Figures in the present application.